REMARKS:

In the Office Action dated April 12, 2006, claims 14 and 60-77, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 14 and 61-77 remain in this application and claims 1-13 and 15-60 have been canceled.

Claims 14 and 60-77 were rejected under 35 USC §112, first paragraph, as lacking enablement. The office action indicates that the previously submitted diagram shows that only a "preformed" biotin-antibody –PEG conjugate having a specific configuration will work to protect the antibody from unspecific interactions. Applicants respectfully point out that schematic drawings always represent a simplification of the subject matter. The drawings only illustrate certain aspects of the invention and are not intended to show the entire invention. In the present invention, any reactant specific for the analyte to be detected can be used. Examples 12 and 13 in the present application show that antigens can be used as analyte-specific reactants. These examples illustrate the procedure for a HIV I test, wherein the presence of HIV antibodies in different samples was determined. According to example 12, an antigen which represents the gp41 of the HIV I virus was immobilized on a support. In example 13, an identical antigen, which was derivatized with PEG, was additionally immobilized on the test support. The prepared solid phase was then contacted with several samples. The detection of antibodies in examples 12 and 13 was performed according to the bridge test format, using Dig-labelled gp41 as a detection antigen. The bridge test format is well known in the art and is described on page 22. In examples 12 and 13 fluorescent

dyed latex particles which are covalently coated with an anti-Dig antibody serve as the detection reagent.

Since only positive samples contain the antibodies to be determined, only these samples result in a signal while negative samples exhibited no reaction in the test zones. In addition, Example 13 shows that the use of the PEG-derivatized antigen results in substantially reduced unspecific binding and a strong increase of the signal of positive samples. Remarks regarding these results can be found on page 26 of the description.

Regarding single epitope antigens, applicants point out that the PEGylation does not interfere with the binding ability of small antigens. It is common knowledge that haptens are small molecules which themselves are not immunogen but can elicit an immune response only when attached to a large carrier. A carrier-bound hapten, however, is simply a single epitope antigen which is bound to a large carrier molecule. As illustrated in example 13, the derivatization of an antigen with PEG in a stoichiometry ratio of 1:1 "was even able to lead to strong increase of the signal of positive samples". Regarding the statement in the office action that the assay of the invention would not be operable in the absence of avidin-biotin binding, applicants point out that this is not correct. Any method for immobilizing the analyte specific reactant would work in the present invention. However, in order to advance the prosecution of the present application, the limitations of claim 60 have been added to claim 14. In view of the above amendments and comments, applicants request that this rejection be withdrawn.

Claims 14 and 60-77 were rejected under 35 USC §112, first paragraph as lacking an adequate written description for a “preformed conjugate” comprised of PEG

and one member of a specific binding pair used as a component of a solid phase assay system. Though a working example is not required for an adequate written description, the present application does indeed include examples where a PEG conjugate is prepared which includes an antibody. Examples 9, 10 and 11 clearly show that biotinylated antibodies are subsequently PEGylated and then tests are carried out to determine blank value and unspecific binding. Example 9 refers to the preparation according to Example 5 except that a biotinylated antibody is used instead of strepatvidin. The synthesis according to Example 5 is based on the reaction of streptavidin and PEG-OSu. Thus, the preparation of example 9 consists in the reaction of a biotinylated antibody with PEG-OSu in order to obtain antibody-PEG-conjugates.

In addition, Tables 6, 7 and 8 show that the additional PEGylation of biotinylated antibodies results in reduced unspecific binding compared to the underivatized antibody. The same applies to example 13 where a biotinylated antigen was subsequently derivatized with PEG 500. Moreover, these PEGylated complexes are described in detail on pages 8 and 9 of the present application. In particular, reference is made to the disclosure on page 9, 2nd par. and page 10, where conjugates of the general structure formula III are described in detail. In view of the above discussed disclosure, applicants request that this rejection be withdrawn.

Claims 60 and 61 were rejected under 35 USC §112, second paragraph, as indefinite. Claim 60 has been canceled and claim 14 amended to indicate that the solid phase is coated with a first member of a high affinity binding pair and said preformed conjugate is immobilized via a high affinity binding pair, wherein the analyte specific reactant in said preformed conjugate is conjugated with a second member of

said high affinity binding pair prior to application of said preformed conjugate to said solid phase. In view of these amendments, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 14 and 61-77 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

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